Paragraph 6009(c)—Amber Federal Airways

A–1 [Revised]

From Sandspit, BC, Canada, NDB 96 miles 12 AGL, 102 miles 35 MSL, 57 miles 12 AGL, via Sitka, AK, NDB; 31 miles 12 AGL, 50 miles 47 MSL, 88 miles 20 MSL, 40 miles 12 AGL, Ocean Cape, AK, NDB; INT Ocean Cape NDB 283° and Hinchinbrook, AK, NDB 106° bearings; Hinchinbrook NDB; INT Hinchinbrook NDB 286° and Campbell Lake, AK, NDB 123° bearings; Campbell Lake NDB; Takotna River, AK, NDB; 24 miles 12 AGL, 53 miles 55 MSL; 51 miles 40 MSL, 25 miles 12 AGL, North River, AK, NDB; 17 miles 12 AGL, 89 miles 25 MSL, 17 miles 12 AGL, to Fort Davis, AK, NDB. That airspace within Canada is excluded.

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Issued in Washington, DC, on December 2, 1997.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 97–32569 Filed 12–11–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 960

[Docket No. 951031259–7103–02]

Licensing of Private Land Remote-Sensing Space Systems

AGENCY: National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice; extension of public comment period.

SUMMARY: Pursuant to public request, the National Oceanic and Atmospheric Administration (NOAA) is extending by 90 days its public comment period for the Notice of Proposed Rulemaking concerning the licensing of private land remote-sensing space systems, published on November 3, 1997, 62 FR 59317.

DATES: Comments must be received by April 2, 1998.

ADDRESSES: Comments should be sent to, Charles Wooldridge, NOAA, National Environmental Satellite, Data, and Information Service, 1315 East-West Highway Room 3620 Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: Charles Wooldridge at (301) 713–2024 ext. 107 or Kira Alvarez, NOAA, Office of General Counsel at (301) 713–1217.

SUPPLEMENTARY INFORMATION: On November 3, 1997, NOAA published a Notice of Proposed Rulemaking (62 FR 59317) proposing regulations revising its regime for the licensing of private Earth remote-sensing space systems under Title II of the Land Remote Sensing Policy Act of 1992, 15 U.S.C. 5601 *et seq.* (1992 Act). These proposed regulations implement the licensing provisions of the 1992 Act and the Presidential Policy announced March 10, 1994. In response to numerous written comments, NOAA is extending the original 60 day public comment period by 90 days. As a result, comments on the notice of proposed rulemaking must now be received by April 2, 1998.

Dated: December 5, 1997.

Gregory W. Withee,

Deputy Assistant Administrator for Satellite and Information Services.

[FR Doc. 97–32472 Filed 12–11–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 97N–0222]

Medical Devices; Preemption of State Product Liability Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding preemption of State and local requirements applicable to medical devices. This action is being taken to clarify and codify the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by February 10, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 521 of the act (21 U.S.C. 360k) contains an express preemption provision applicable to medical devices regulated by FDA. The Supreme Court recently addressed whether section 521 of the act preempts State common law tort claims arising from allegedly defective medical devices. (See *Medtronic, Inc.* v. *Lohr (Lohr)*, 116 S. Ct. 2240 (1996).) The Court concluded that section 521 of the act did not supplant the State law duties at issue in that case. In reaching that conclusion, the Court noted that FDA has provided interpretive guidance with respect to section 521 of the act's preemptive effect. (See *id.* at 2255–2256 (citing 21 CFR 808.1(d)(2) and 808.5(b)(1)(i) (1995)).) The Court gave ''substantial weight to the agency's view of the statute'' (*Id.* at 2256). (See also *id.* at 2257; *id.* at 2260–2261 (Breyer, J., concurring in part and concurring in the judgment).)

The Court's decision in *Lohr* construed section 521 of the act in the context of a medical device that FDA had cleared for distribution under section 510(k) of the act (21 U.S.C. 360k), which requires premarket notification for certain types of medical devices. The Court did not definitively decide whether section 521 of the act may preempt State law claims in other circumstances. Since *Lohr* was decided, the lower courts have interpreted section 521 of the act inconsistently and have reached conflicting conclusions with respect to whether section 521 of the act preempts State law claims for injuries allegedly resulting from medical devices that have received premarket approval under section 515 of the act (21 U.S.C. 360e), or have received an investigational device exemption (IDE) under section 520(g) of the act (21 U.S.C. 360j(g)).

In light of the confusion among the lower courts in interpreting section 521 of the act since *Lohr*, and in accordance with the Supreme Court's recognition that FDA's interpretation of the preemptive effect of section 521 is entitled to substantial weight, the agency is issuing this proposed interpretive rule, which addresses the circumstances in which section 521 of the act preempts State common tort claims based on injury from allegedly defective medical devices.

II. Background

Congress enacted the Medical Device Amendments of 1976 (the amendments) (21 U.S.C. 360c *et seq.*), ''to provide for the safety and effectiveness of medical devices intended for human use.'' It